DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: 02-003

2. STATE: Minnesota

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
March 11, 2002

5. TYPE OF PLAN MATERIAL *(Check One)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION:
42 CFR 440.120 (a)

7. FEDERAL BUDGET IMPACT:
a. FFY '02 $ ($950)
b. FFY '03 $ ($1640)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Att. 3.1-A, pp. 46-46e
Att. 3.1-B, pp. 45-45e

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Att. 3.1-A, pp. 46-46e
Att. 3.1-B, pp. 45-45e

10. SUBJECT OF AMENDMENT:

Services: Prescribed Drugs

11. GOVERNOR'S REVIEW *(Check One)*:

☒ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☐ OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL:
Mary B Kennedy

13. TYPED NAME:
Mary Kennedy

14. TITLE:
Medicaid Director

15. DATE SUBMITTED: 3/27/02

16. RETURN TO:
Stephanie Schwartz
444 Lafayette Road North
St. Paul, MN 55155-3852

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 3/28/02

18. DATE APPROVED: 8/27/02

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
March 11, 2002

20. SIGNATURE OF REGIONAL OFFICIAL:
Cheryl A Harris

21. TYPED NAME:
Cheryl A. Harris

22. TITLE:
Associate Regional Administrator
Division of Medicaid and Children's Health

23. REMARKS:

RECEIVED
MAR 28 2002
DMCH - MI/MN/WI

FORM HCFA-179 (07-92)

Instructions on Back

MINNESOTA

MEDICAL ASSISTANCE

Federal Budget Impact of Proposed State Plan Amendment TN 02-03

Attachment 3.1-A/B: Prescribed Drugs

Effective March 11, 2002, six new drugs require prior authorization. These drugs are subject to inappropriate use and are expensive.

The Department estimates the federal budget savings as follows:

	FFY '02*	FFY '03
State savings	$ 950,000	$1,640,000
Federal savings	**$ 950,000**	**$1,640,000**
Total MA Savings	$1,900,000	$3,280,000

*March 11, 2002 through September 30, 2002

12.a. Prescribed drugs.

The following providers are eligible for payment for dispensing prescribed drugs:

(1) A pharmacy that is licensed by the Minnesota Board of Pharmacy.
(2) An out of state pharmacy that complies with the licensing and certification requirements of the state in which it is located.
(3) A physician located in a local trade area where there is no Medicaid enrolled pharmacy. To be eligible for payment, the physician shall personally dispense the prescribed drug according to applicable Minnesota Statutes and shall adhere to the labeling requirements of the Minnesota Board of Pharmacy.
(4) A physician or nurse practitioner employed by or under contract with a community health board, for the purposes of communicable disease control.

The following limitations apply to pharmacy services:

(1) With the exception noted below, the prescribed drug must be a drug or compounded prescription that is made by a manufacturer that has a rebate with the Health Care Financing Administration (HCFA) and included in the Minnesota Department of Human Services drug formulary. The formulary is established in accordance with §1927 of the Social Security Act. See Drug Formulary.

A prescribed drug is covered if it has Investigational New Drug (IND) status with an IND number by the United States Food and Drug Administration (FDA), even though the manufacturer does not have a rebate with HCFA. When the prescribed drug receives FDA approval, the manufacturer must have a rebate agreement for the drug in order for the drug to be covered.

(2) A prescribed drug must be dispensed in the quantity specified on the prescription unless the pharmacy is using unit dose dispensing or the specified quantity is not available in the pharmacy when the prescription is dispensed. Only one dispensing fee is allowed for dispensing the quantity specified on the prescription.

12.a. Prescribed drugs. (continued)

(3) The dispensed quantity of a prescribed drug must not exceed a three-month supply.

(4) An initial or refill prescription for a maintenance drug shall be dispensed in not less than a 30-day supply unless the pharmacy is using unit dose dispensing. No additional dispensing fee shall be paid until that quantity is used by the recipient.

(5) Except as provided in item (6), coverage of the dispensing fee for a particular pharmacy or dispensing physician for a maintenance drug for a recipient is limited to one fee per 30-day supply.

(6) More than one dispensing fee per calendar month for a maintenance drug for a recipient is allowed if:

(a) the record kept by the pharmacist or dispensing physician documents that there is a significant chance of overdosage by the recipient if a larger quantity of drug is dispensed, and if the pharmacist or dispensing physician writes a statement of this reason on the prescription; or

(b) the drug is clozapine.

(7) A refill of a prescription must be authorized by the practitioner. Refilled prescriptions must be documented in the prescription file, initialed by the pharmacist who refills the prescription, and approved by the practitioner as consistent with accepted pharmacy practice under Minnesota Statutes.

(8) Generic drugs must be dispensed to recipients if:

(a) the generically equivalent drug is approved and is determined as therapeutically equivalent by the FDA;

12.a. Prescribed drugs. (continued)

(b) in the pharmacist's or dispensing physician's professional judgment, the generically equivalent drug is safely interchangeable with the prescribed drug;

(c) the charge for the substituted generically equivalent drug does not exceed the charge for the drug originally prescribed; and

(d) the practitioner has not written in his or her own handwriting "Dispense as Written-Brand Necessary" or "DAW-Brand Necessary" on the prescription.

(9) Over the counter medications must be dispensed in the manufacturer's unopened package, except that Sorbitol may be repackaged.

(10) The following limits apply to drugs dispensed under unit dose packaging:

(a) Dispensing fees for drugs dispensed in unit dose packaging shall not be paid more often than once per calendar month or when a minimum of 30 dosage units have been dispensed, whichever results in the lesser number of dispensing fees.

(b) Only one dispensing fee per calendar month will be paid for each maintenance drug, regardless of the type of unit dose system used or the number of times during the month the pharmacist dispenses the drug.

(c) An additional dispensing fee per prescription shall be paid to pharmacists using an in-pharmacy packaged unit dose system (except for over-the-counter [OTC] medications) approved by the Board of Pharmacy for the return of drugs when dispensing to recipients in a long-term care facility if:

(i) the pharmacy is registered with the Department by filing an addendum to the provider agreement;

12.a. Prescribed drugs. (continued)

(ii) a minimum 30-day supply of the drug is dispensed, although a lesser quantity may be dispensed for an acute course of medication therapy for a specified time period;

(iii) the national drug code from the drug stock container used to fill the unit dose package is identified to the Department;

(iv) the unit dose package containing the drug meets the packaging standards set forth in Minnesota Statutes that govern the return of unused drugs to the pharmacy for reuse and documentation that unit dose packaging meets permeability standards of the Board of Pharmacy; and

(v) the pharmacy provider credits the Department for the actual acquisition cost of all unused drugs that are eligible for return and reuse.

(11) Delivery charges for a drug are not covered.

Drug Formulary:

All drugs and compounded prescriptions made by a manufacturer that are covered under a signed rebate agreement with HCFA are included in the drug formulary, with the following three limitations on coverage:

(1) The following drugs require prior authorization:

(a) Alglucerase (Ceredase)
(b) Botulinum Toxin Type A (Botox)
(c) Interferon Alfa-n3 (Alferon N)
(d) Interferon Gamma-1b (Actimmune)
(e) Lansoprazole (Prevacid)~~: for > 4 consecutive weeks continuous treatment~~
(f) Omeprazole (Prilosec)~~: for > 4 consecutive weeks continuous treatment~~
(g) Ondansetron (Zofran): for > 4 consecutive weeks continuous treatment

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ATTACHMENT 3.1-A
Page 46d

12.a. Prescribed drugs. (continued)

(h) Rabeprazole (Aciphex)
(i) Sertraline (Zoloft), 25 and 50 mg.
(j) Dolasetron (Anzemet): for > 4 consecutive weeks continuous treatment
(k) Botulinum Toxin Type B (Myobloc)
(l) Celecoxib (Celebrex)
(m) Granisetron (Kytril): for > 4 consecutive weeks continuous treatment
(n) Esomeprazole (Nexium)
(o) Rofecoxib (Vioxx)

(2) The following categories of drugs subject to restriction under §1927(d)(2) are not covered:

(a) Agents when used for anorexia, except that medically necessary anorectics are covered for recipients previously diagnosed as having pickwickian syndrome and currently diagnosed as having diabetes and being morbidly obese.

(b) Agents when used to promote fertility.

(c) Agents when used for cosmetic purposes or hair growth.

(d) Covered outpatient drugs that the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(e) Drugs described in §107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (within the meaning of 21 CFR §310.6(b)(1) (DESI drugs)).

(3) The following categories of drugs subject to restriction under §1927(d)(2) are covered with limitations:

(a) Agents when used for the symptomatic relief of cough and colds must be listed in the Department's "Minnesota Health Care Programs Provider Manual," on a remittance advice message, or in a Department-issued provider update.

12.a. Prescribed drugs. (continued)

(b) Nonprescription drugs must be listed in the Department's "Health Care Programs Provider Manual," on a remittance advice message, or in a Department-issued provider update.

(c) Prescription vitamins and mineral products for children, pregnant and nursing women, and recipients with documented vitamin deficiencies. The limitations do not apply to fluoride treatments. Prenatal vitamins are restricted to pregnant and nursing women.

Notwithstanding the above paragraph, some vitamins and mineral products are available for the treatment or prevention of certain diseases:

(1) niacin;

(2) calcium and calcium/vitamin D; and

(3) generic preparations equivalent to Ocuvite.

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ATTACHMENT 3.1-B
Page 45d

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ATTACHMENT 3.1-B
Page 45e

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